FDA Patient Safety News: Show #10, November 2002

New Preservative-free Flu Vaccine Approved

The FDA recently approved an influenza vaccine that does not contain thimerosal as a preservative and can be used for young children, those six months or older. It's called Fluzone, and it's manufactured by Aventis Pasteur, Incorporated.

Previously, FDA approved another flu vaccine that does not contain thimerosal as a preservative, and it's indicated for persons four years and older. It's called Fluvarin, manufactured by Evans Vaccines Limited. Both of these vaccines are available in single-dose units that contain only a trace amount of thimerosal, and they continue to be available in multi-dose vials that do contain thimerosal as a preservative.

Thimerosal contains mercury. It's been commonly used as a preservative in vaccines since the 1930's. Although the small amounts of mercury that patients would receive from vaccines have not been shown to be harmful, reducing mercury exposure from all sources, including food, medical products, and the general environment, is an important public health goal. And so FDA has been working with manufacturers to reduce or eliminate the use of thimerosal as a preservative in drugs and vaccines. With the approval of Fluzone, practitioners now have an additional way to help minimize mercury exposure in young children.

Additional Information:

Product Approval Information - Licensing Action.
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm112854.htm

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Additional Information:

Thimerosal in Vaccines.
http://www.fda.gov/cber/vaccine/thimerosal.htm#act

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Additional Information:

Thimerosal in Vaccines- Frequently Asked Questions.
http://www.fda.gov/cber/vaccine/thimfaq.htm

Drug Name Confusion: Serzone and Seroquel

Drug names, particularly proprietary names, can look or sound alike. When one drug is mistaken for another, serious patient injuries can occur. Take the case of Serzone and Seroquel. Serzone, manufactured by Bristol-Myers Squibb, is approved to treat depression. Seroquel, made by Astra-Zeneca, is indicated for treating schizophrenia.

FDA has received several dozen reports of medication error where these two drugs were mixed up. Because of the similarity in the sound and look of the two names, pharmacists incorrectly

interpreted written and verbal prescriptions. They also labeled and filled them incorrectly- Serzone for Seroquel, and vice versa. Patients who received the wrong drug suffered a variety of adverse events. Several required emergency room visits, and a few were hospitalized.

Besides the similar sounding names, other factors contributed to the confusion. For example, both Serzone and Seroquel are taken orally, both are prescribed BID, and there's some overlap in the available strengths of the two drugs. And because both names start with the same three letters, they are stored next to each other on pharmacy shelves, further increasing the risk of errors. Even the distinctive appearance of the Serzone and Seroquel tablets did not prevent the errors. In several incidents, the pharmacists placed Seroquel in a pharmacy bottle labeled Serzone, or vice versa, because they selected the wrong product from the pharmacy shelf.

Here are ways to help prevent these kinds of name confusion errors:

* Educate the staff about the medication errors caused by name confusion.
* Verify all orders between pharmacists and prescribers by spelling both the proprietary name and the generic name.
* Counsel patients in detail about their prescribed drug.
* When drug names can be easily confused, consider using computerized name alerts as well as reminders on drug containers and drug storage shelves.
* And separate look-alike or sound-alike drugs on the shelves

Additional Information:

Medication Errors.
http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/default.htm

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Update on Cochlear Implants and Meningitis

In a previous broadcast, we reported on a possible association between cochlear implants and bacterial meningitis. Since then, FDA has received reports of additional cases of meningitis in cochlear implant patients.
It's still not certain whether the implants themselves are raising the risk of meningitis, by serving as a focal point for infection, or whether some predisposing factor might be responsible. For example, some deaf patients may have congenital abnormalities of the inner ear which make them more susceptible to meningitis. Or, patients might have had otitis media prior to the surgery.

Our notification recommended that physicians consider prophylactic antibiotic treatment prior to implanting these devices and that they promptly diagnose and treat otitis media in patients who already have the implants.

It also suggested that cochlear implant recipients might benefit from vaccinations against the organisms that commonly cause bacterial meningitis.

Since our last story, the FDA, CDC and state health departments have begun a comprehensive investigation of the apparent association between meningitis and cochlear implantation. This study focuses on children under 6 who have the implants.

The CDC has a special phone number to report cases of meningitis in implant patients - so they can be included in this study. CDC also has a telephone hotline to advise persons with cochlear implants on appropriate immunizations. You can also find both phone numbers on our website.

Additional Information:

FDA Public Health Web Notification: Cochlear Implant Recipients may be at Greater Risk for Meningitis.
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/UCM062104

Possible Risks Associated With IGIV

FDA has received reports of serious thrombotic events occurring in patients following administration of Immune Globulin Intravenous, or IGIV. At this point, we don't know if these thrombotic events were caused by IGIV administration. And we don't have sufficient evidence to tie these events to a specific characteristic of IGIV products, such as excipients, concentration, or traces of procoagulants.

Although the cause of this problem is still unclear, you should be aware that rapid infusion rates and high doses of IGIV might be potential risk factors for this complication in patients who are already at risk for thrombotic events.

FDA will continue to investigate these reports, and we'll keep you informed in future broadcasts.

Additional Information:

FDA MedWatch Safety Information Summary.
http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/UCM154878.pdf

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LASIK Eye Surgery Website

LASIK eye surgery is a popular elective procedure intended to reduce a person's dependency on glasses or contact lenses, and some of your patients may be asking you about the procedure. FDA has a consumer website on LASIK surgery, and it's recently been updated with additional information and helpful tips.

LASIK surgery corrects refractive errors in the eye by reshaping the cornea. Using an excimer laser, precise amounts of corneal tissue are removed, and this changes its focusing power.

Here's how the procedure is done. A microkeratome is used to cut a flap in the cornea, with a hinge left at one end of this flap. The flap is folded back revealing the stroma - the middlesection of the cornea. Pulses from a computer-controlled laser vaporize a portion of the stroma and the flap is replaced.

The website provides helpful tips for choosing the right doctor. It also gives a list of factors that will help potential patients decide if they're good candidates for the procedure. The website points out that patients with refractive instability may face additional risks. These patients include those in their early 20's or younger, those whose hormones are fluctuating due to disease such as diabetes, those who are pregnant or breast feeding, and those who are taking medications that may cause fluctuation in vision.

Patients who should avoid LASIK surgery entirely include those with a history of herpes in the eye area, glaucoma, certain eye diseases, or eye injuries.

The website encourages patients to carefully weigh all of the risks and benefits of the surgery. It points out that even with surgery, patients should be aware that they may not achieve 20/20 vision, and may still require glasses or contact lenses. The surgery could cause patients to lose some vision that's not correctable with glasses, contact lenses or additional surgery.

Additional Information:

LASIK Eye Surgery Consumer web site.
http://www.fda.gov/cdrh/LASIK/

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Additional Information:

Updates.
http://www.fda.gov/cdrh/LASIK/updates.htm

AED's are Becoming More Visible in Public Places

Your patients may be noticing devices located in health clubs, hotels and airports called Automated External Defibrillators or AED's. They may be wondering whether they should try to use them in an emergency, and if so, how.

These devices are designed to be as easy to use as possible. For example, they only advise the operator that a shock is needed when a patient is in ventricular fibrillation or fast ventricular tachycardia.

But still, they should only be used by people who've received some training. The American Heart Association recommends that people who live or work in a place that has one of these devices, participate in a Heartsaver AED course. The course explains the Chain of Survival and how important the AED is in that chain.

In the course, your patients will learn that the first step in an emergency is to call 911 and send someone to get the AED. Then they should administer CPR until the AED arrives and continue using the AED and CPR until emergency personnel get there. They'll also be cautioned that the AED should not be used on a child younger than 8 years old.

The AHA offers these courses through local Community Training Centers. If your patients are interested in learning more about public access defibrillators, refer them to our website, where there's a link to the AHA's website.

By the way, if you're interested in having one of these defibrillators installed in a public facility near you, you may be able to arrange that through the AHA. A physician must issue a prescription for a facility to purchase the device. You can get more information on this from the AHA's web site.

Additional Information:

American Heart Association CPR and AEDs.
http://www.cpr-ecc.org/cpr_aed/cpr_aed_menu.htm

FDA Patient Safety News is available at www.fda.gov/psn